

DN CV 14 6025333 S

STAMFORD HEALTH SYSTEM, INC.)	SUPERIOR COURT
D/B/A STAMFORD HOSPITAL)	
)	J.D. OF WATERBURY @
v.)	WATERBURY
)	
ETHICON, INC., ET AL.)	NOVEMBER 20, 2015

DEFENDANT AMERICAN MEDICAL SYSTEM'S
ANSWER AND SPECIAL DEFENSES TO THIRD PARTY COMPLAINT DATED
AUGUST 13, 2015

Defendant Astora Women's Health, LLC (hereinafter "AMS"), improperly identified as American Medical Systems, Inc., by and through undersigned counsel, hereby answers and responds to the Complaint of Stamford Health System, Inc. D/B/A Stamford Hospital as follows:

1. As to the allegations contained in Paragraph 1, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

2. As to the allegations contained in Paragraph 2, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

3-6. The allegations contained in Paragraph 3-6 are directed to a party other than AMS and therefore AMS does not respond. To the extent a response is necessary, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

7. Denied as stated. Due to corporate restructurings, as of September 29, 2015 the women's health business formerly conducted by American Medical Systems, Inc. (now known as American Medical Systems, LLC) and its subsidiaries is conducted by Astora Women's Health LLC, which is a wholly owned subsidiary of Astora Women's Health, Inc. (formerly known as American Medical Systems Holdings, Inc.). Astora Women's Health, Inc. is a majority-owned subsidiary of Endo Pharmaceuticals, Inc., which is a wholly owned subsidiary of Endo Health Solutions Inc. (formerly known as Endo Pharmaceuticals Holdings, Inc.), whose ultimate parent is Endo International plc, a publicly traded company.

8. Denied as stated. Due to corporate restructurings, as of September 29, 2015 the women's health business formerly conducted by American Medical Systems, Inc. (now known as American Medical Systems, LLC) and its subsidiaries is conducted by Astora Women's Health LLC, which is a wholly owned subsidiary of Astora Women's Health, Inc. (formerly known as American Medical Systems Holdings, Inc.). Astora Women's Health, Inc. is a majority-owned subsidiary of Endo Pharmaceuticals, Inc., which is a wholly owned subsidiary of Endo Health Solutions Inc. (formerly known as Endo Pharmaceuticals Holdings, Inc.), whose ultimate parent is Endo International plc, a publicly traded company.

9. The allegations contained in Paragraph 9 are admitted in part and denied in part. So much of Paragraph 9 as alleges that AMS sells a product known as Monarc, the allegations are admitted. As to the remaining allegations set forth, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof

Count One: Product Liability

10. The allegations contained in Paragraph 10 are legal conclusions and therefore AMS does not respond. To the extent a response is necessary, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

11. As to the allegations contained in Paragraph 11, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

12-18. As to the allegations contained in Paragraphs 12-18, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of these Paragraphs of the Complaint and therefore the Plaintiffs are left to their proof. By way of further response, the allegations in this Paragraph pertain to writings that speak for themselves and any attempts to characterize them are denied. Furthermore, AMS expressly denies that any of its products are defective or caused injuries to Ms. Sherwood or the third party Plaintiff.

19. As to the allegations contained in Paragraph 19, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

20. As to the allegations contained in Paragraph 20, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof.

21. As to the allegations contained in Paragraph 21, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of these Paragraphs of the Complaint and therefore the Plaintiffs are left to their proof. By way of further response, the allegations in this Paragraph pertain to writings that speak for themselves and any attempts to characterize them are denied. Furthermore, AMS expressly denies that any of its products are defective or caused injuries to Ms. Sherwood or the third party Plaintiff.

22. The allegations contained in Paragraph 22 (and its subparts) are legal conclusions and therefore AMS does not respond. To the extent a response is necessary, AMS is without knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph of the Complaint and therefore the Plaintiffs are left to their proof. By way of further response, the allegations in this Paragraph pertain to writings that speak for themselves and any attempts to characterize them are denied. Furthermore, AMS expressly denies that any of its products are defective or caused injuries to Ms. Sherwood or the third party Plaintiff.

23. The allegations contained in Paragraph 23 are legal conclusions and therefore AMS does not respond. To the extent a response is necessary, AMS expressly denies that any of its products are defective or caused injuries to Ms. Sherwood or the third party Plaintiff.

SPECIAL DEFENSES

AMS alleges and asserts the following special defenses in response to the allegations in the Complaint.

FIRST DEFENSE

The Complaint fails to state a claim or claims upon which relief can be granted.

SECOND DEFENSE

The Complaint fails to state a claim or claims upon which relief can be granted due to lack of adequate product identification.

THIRD DEFENSE

The Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because the Plaintiffs may lack standing and/or capacity to bring such claims.

FOURTH DEFENSE

This Court lacks personal jurisdiction over AMS such that AMS should be dismissed. AMS specifically raises this defense, makes it objections to the exercise of personal jurisdiction over AMS in this Court, and preserves its rights to seek dismissal by way of subsequent motion.

FIFTH DEFENSE

The sole proximate cause of the Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions AMS was and is in no way liable.

SIXTH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, any recovery by the Plaintiffs is barred to the extent they voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent the Plaintiffs have failed to mitigate their alleged damages,

any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

SEVENTH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, such damages were only sustained after Plaintiffs knowingly and voluntarily assumed the risk of such injury, loss, and damages as the result of the implantation of the pelvic mesh products designed to treat pelvic disorders as prescribed by the Plaintiffs' physicians. Accordingly, Plaintiffs' claims are barred, in whole or in part, by principles of assumption of the risk and informed consent.

EIGHTH DEFENSE

The Plaintiffs failed to exercise ordinary care for their own safety such that the Plaintiffs are not entitled to recover.

NINTH DEFENSE

The injuries and damages allegedly sustained by the Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in the Plaintiffs over which AMS had no control.

TENTH DEFENSE

Some or all of Plaintiffs' claims are barred because any damage, loss, or injury allegedly resulting from the implantation of any products were proximately caused by substantial or material alteration or modification of the Product after the Product left the control of AMS.

ELEVENTH DEFENSE

Any AMS component involved in this action was fitted to and implanted into the Plaintiff's body by a licensed physician after it left control of AMS, and to the extent supported by the facts of the case, some or all of Plaintiff's claims are barred by changes to the condition of the product after it left control of AMS.

TWELFTH DEFENSE

The Plaintiffs' causes of action may be barred by the applicable statute of limitations and/or statute of repose.

THIRTEENTH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, waiver, estoppel and/or regulatory compliance.

FOURTEENTH DEFENSE

There was no defect in the products at issue with the result that the Plaintiffs are not entitled to recover against AMS.

FIFTEENTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and Plaintiffs' alleged damages with the result that Plaintiffs are not entitled to recover against AMS.

SIXTEENTH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, such damages were caused by the negligence or fault of the Plaintiffs.

SEVENTEENTH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, such damages were caused by the negligence or fault of persons and/or entities for whose conduct AMS is not legally responsible.

EIGHTEENTH DEFENSE

If the Plaintiffs suffered any damages or injuries, which are denied, the Plaintiffs' recovery is barred, in whole or in part, or subject to reduction under the doctrine of contributory and/or comparative negligence.

NINETEENTH DEFENSE

In the alternative, and only in the event that it is determined that the Plaintiffs are entitled to recover against AMS, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiffs, any other defendants, third party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the Plaintiffs have settled or may settle in the future.

TWENTIETH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, the negligence or fault of the Plaintiffs constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

TWENTY-FIRST DEFENSE

If the Plaintiffs have been damaged, which AMS denies, the negligence or fault of persons and/or entities for whose conduct AMS is not legally responsible constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

TWENTY-SECOND DEFENSE

If the Plaintiffs have been damaged, which AMS denies, the actions of persons or entities for whose conduct AMS is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of the Plaintiffs' alleged damages.

TWENTY-THIRD DEFENSE

If the Plaintiffs have been damaged, which AMS denies, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which AMS is not legally responsible.

TWENTY-FOURTH DEFENSE

If the Plaintiffs have been damaged, which AMS denies, such damages were caused by abuse, misuse, user error and/or modification of the products at issue for which AMS was and is in no way liable.

TWENTY-FIFTH DEFENSE

AMS made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the Plaintiffs. To the extent applicable, the

Plaintiffs' breach of warranty claims are barred by a lack of privity between the Plaintiffs and AMS. To the extent the Plaintiffs made warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the Plaintiffs' lack of reliance on any such warranties, and by waiver.

TWENTY-SIXTH DEFENSE

To the extent the Plaintiffs assert a claim for breach of implied warranty, such claim must fail because the products were not used for their ordinary purpose.

TWENTY-SEVENTH DEFENSE

To the extent the Plaintiffs assert a claim for breach of warranty, such claim is barred because the Plaintiffs did not first give notice of any alleged defect of the products to AMS.

TWENTY-EIGHTH DEFENSE

AMS neither had nor breached any alleged duty to warn with respect to the products, with the result that the Plaintiffs are not entitled to recover in this cause.

TWENTY-NINTH DEFENSE

The Plaintiffs' claims are barred by the learned intermediary doctrine.

THIRTIETH DEFENSE

The conduct of AMS and the subject products at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statute and regulations. Accordingly, the Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal

laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

THIRTY-FIRST DEFENSE

Plaintiffs may not assert a claim based on alleged fraud on the FDA.

THIRTY-SECOND DEFENSE

If the Plaintiffs recover from AMS, it is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiffs' alleged damages.

THIRTY-THIRD DEFENSE

The Plaintiffs' claims are or may be barred, in whole or in part, to the extent that the Plaintiffs have released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. AMS is entitled to a set-off for the entire amount of proceeds the Plaintiffs have or may recover from all other sources.

THIRTY-FOUR DEFENSE

Should AMS be held liable to the Plaintiffs, which liability is specifically denied, AMS would be entitled to a set-off for the total of all amounts paid to the Plaintiffs from all collateral sources.

THIRTY-FIVE DEFENSE

Plaintiffs' damages claims are barred by the economic loss doctrine.

THIRTY-SIX DEFENSE

AMS asserts any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserves the right to amend its Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-SEVENTH DEFENSE

The products at issue are neither defective nor unreasonably dangerous because it is a medical device falling within what is commonly known as Comments (j) and (k), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the products at issue were, at all times material to the Complaint, reasonably safe and reasonably fit for their intended use, and the warnings and instructions accompanying the products at the time of the occurrence or injuries alleged by the Plaintiffs were legally adequate.

THIRTY-EIGHTH DEFENSE

The Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the products were manufactured and marketed.

THIRTY-NINTH DEFENSE

The Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

FORTIETH DEFENSE

The design complained of in the Complaint, the alleged defects of the products, and/or any alternative design claimed by the Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

FORTY-FIRST DEFENSE

Plaintiffs' causes of action are barred in whole or in part by their failure to assert a safer design for the Product.

FORTY-SECOND DEFENSE

AMS specifically pleads all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC § 2-607.

FORTY-THIRD DEFENSE

No act or omission of AMS was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

FORTY-FOURTH DEFENSE

To the extent the Plaintiffs assert a demand for punitive damages, AMS specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

FORTY-FIFTH DEFENSE

To the extent that the Plaintiffs assert a claim for punitive damages, that claim is in contravention of the rights of AMS under the following constitutional provisions:

1. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the applicable State Constitutions, on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;
- (c) the procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;
- (f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the

same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

- (g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;
- (h) the award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law; and
- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTY-SIXTH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, because Plaintiffs assumed the risks disclosed by the FDA-approved product labeling, the prescribing physicians, or other persons or entities.

FORTY-SEVENTH DEFENSE

There should be no recovery against AMS for any failure to warn or inadequacy of warning, because at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for warning.

FORTY-EIGHTH DEFENSE

If Plaintiffs were injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product manufactured by AMS.

FORTY-NINTH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, because AMS at all relevant times, complied with all applicable laws and regulations.

FIFTIETH DEFENSE

The Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

FIFTY-FIRST DEFENSE

Venue may be improper in any individual case where the Plaintiffs do not reside in the forum wherein her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

FIFTY-SECOND DEFENSE

Plaintiffs' case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

FIFTY-THIRD DEFENSE

AMS is entitled to and claims the benefits of all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

FIFTY-FOURTH DEFENSE

The Plaintiffs have failed to plead their fraud claims with the particularity required under the applicable state's statutory and/or common law.

FIFTY-FIFTH DEFENSE

If it should be proven that any product distributed by AMS was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that AMS neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

FIFTY-SIXTH DEFENSE

AMS used reasonable care to inform the medical community of, inter alia, the indications, contraindications and risks of its medical devices, including Pelvic Mesh Products.

FIFTY-SEVENTH DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

FIFTY-EIGHTH DEFENSE

Plaintiffs' claims may be barred by failure to join indispensable parties.

FIFTY-NINTH DEFENSE

AMS intends to rely upon any additional affirmative defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

SIXTIETH DEFENSE

AMS hereby gives notice that it intends to rely upon and incorporates by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

WHEREFORE, AMS avers that Plaintiffs are not entitled to the relief demanded in the Complaint, and AMS, having fully answered, prays that this action against it be dismissed and that it be awarded its costs in defending this action and that it be granted such other and further relief as the Court deems just and appropriate.

THIRD PARTY DEFENDANTS
AMERICAN MEDICAL SYSTEMS, INC.
AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.

BY: 

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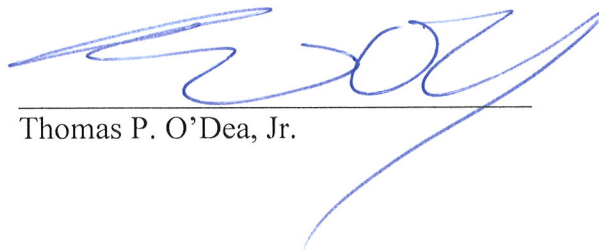
CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was on this November 29, 2015 to all counsel and parties of record as follows:

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